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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/735,251      | 12/12/2000  | Guy Reed             | 21509-020 Div.      | 7325             |

7590

06/20/2002

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EXAMINER

HADDAD, MAHER M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 06/20/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/735,251

Applicant(s)

REED ET AL.

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12-12, 00, 3-2-01 and 04-8-02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-17, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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#### DETAILED ACTION

1. Claims 9-21 are pending.
2. Applicant's election without traverse of Group I, claims 9-10 and 18-19 in Paper No. 11 is acknowledged.
3. Claims 11-17 and 20-21 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 9-10 and 18-19 are under examination.
5. The preliminary amendment filed 3-2-01 to page 1, line 5, is acknowledged. However, the U.S. Serial No. **09/725,758** should be amended to **08/725,758**.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112.  
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*
7. Claim 19 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A) Claim 19 is indefinite in the recitation of "MAb 3B2" because the monoclonal antibody characteristics are not known. The use of "MAb 3B2" as the sole means of identifying the claimed polypeptide renders the claim indefinite because it is merely laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct cell line. Amending the claim to recite the appropriate ATCC Accession Number would obviate this rejection.

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## 8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

9. Claims 9 and 18-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO:4 encoded by the DNA of SEQ ID NO:3 for generating antibodies diagnostic for activated platelets and for thrombus; does not reasonably provide enablement for any substantially pure polypeptide comprising a sequence identical to at least 95% of SEQ ID NO:4 in claim 9; any polypeptide comprising any antigenic fragment of the polypeptide in claim 18; or any substantially pure polypeptide having the sequence of a naturally-occurring platelet activation polypeptide that comprises any epitope which binds to MAb 3B2 in claim 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention. The specification discloses only a single polypeptide sequence (SEQ ID NO:4) encoded by a single DNA of (SEQ ID NO:3) with a disclosed utility in generating antibodies diagnostic for activated platelets and for thrombus (e.g., page 7 at lines 25-27). The instant claims encompass in their breadth any polypeptide comprising a sequence identical to at least 95% of SEQ ID NO:4; any polypeptide comprising any "antigenic fragment"; or any polypeptide comprises any "epitope which binds to MAb 3B2".

The terms "comprising" and "having" in claims 9 and 18-19 are open-ended, they expand the polypeptide of SEQ ID NO: 4 to include additional non disclosed amino acids. There appears to be insufficient guidance in the specification as filed as to how the skilled artisan would make and use the various amino acids recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequence. Without detailed direction as to which amino acid sequences are essential to the function of the encoded polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of amino acid sequences are encompassed by the instant claims

The skilled artisan would not reasonably expect a polypeptide having anything less than 100% identity *over the full length of SEQ ID NO: 4 to share the same function* as the polypeptide of SEQ ID NO:4. Because of the unpredictability and lack of guidance, an undue experimentation would be required to determine which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo *et al* in the Protein Folding problem and Tertiary Structure prediction, 1994, Merz *et al.*, (ed), Birkhauser, Boston, MA, pp.433 and 492-495), it would require an undue amount of experimentation for on of skill in the art to arrive at the claimed

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polypeptide having the sequence of a naturally-occurring platelet activation polypeptide that comprises an epitope which binds to MAb 3B2; or a polypeptide comprising a sequence identical to at least 95% of SEQ ID NO:4 or its antigenic fragments encompassed by the claimed invention.

The ultimate use of the claimed polypeptide is to make antibody then any change in the claimed polypeptide of SEQ ID NO: 4 would affect the binding specificity of the antibody. Colman *et al* in Research in Immunology (145(1):33-36, 1994) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza *et al* in Journal of Protein Chemistry (11(5):433-444, 1992) teach that single amino acid substitutions outside the antigenic site on a protein effect antibody binding. Futher, Lederman *et al* in Molecular Immunology (28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Additionally, Li *et al* in PNAS (77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the instantly recited amino acid sequences and still maintain the functional properties of the polypeptide of SEQ ID NO:4 is unpredictable; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

10. Claims 9 and 18-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of polypeptide of SEQ ID NO: 4 encoded by nucleic acid of SEQ ID NO:3.

Applicant is not in possession of any polypeptide comprising sequence identical to at least 95% of SEQ ID NO:4 in claim 9; any polypeptide comprising any antigenic fragment of the polypeptide in claim 18; or any substantially pure polypeptide having the sequence of a naturally-occurring platelet activation polypeptide that comprises any epitope which binds to Mab 3B2 in claim 19.

Applicant has disclosed only polypeptide of SEQ ID NO: 4; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written

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description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

12. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Docherty et al 1985.

The Docherty *et al* teach a 207 amino acid polypeptide comprising an antigenic fragment of the claimed polypeptide of SEQ ID NO:4 at positions (46-52) (see sequence alignment in particular). The term "comprising" in the instant claim 18 is open-ended; it would open up the claim to include the reference 207 amino acid sequence.

The reference teachings anticipate the claimed invention.

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13. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by WO9406919 publication (March 1994).

The '919 publication teaches a 604 amino acid polypeptide comprising an antigenic fragment of the claimed polypeptide of SEQ ID NO:4 at positions (54-61) (see pages 45-47 and sequence alignment in particular). The term "comprising" in the instant claim 18 is open-ended; it would open up the claim to include the reference 604 amino acid sequence.

The reference teachings anticipate the claimed invention.

14. It appears that the polypeptide of SEQ ID NO:4 encoded by SEQ ID NO:3 is free of prior art.

15. Claim 10 is objected to as being dependent upon a rejected base claim 9, but would be allowable if rewritten in independent form.

16. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

**17. 1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**


Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.  
Patent Examiner  
Technology Center 1600  
June 17, 2002

  
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